इंटरनेट मानक

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IS 8585 (1977): Bougie, Oesophageal [MHD 1: Surgical Instruments]

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Bhartṛhari—Nītiśatakam
“Knowledge is such a treasure which cannot be stolen”

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IS : 8585 - 1977

Indian Standard

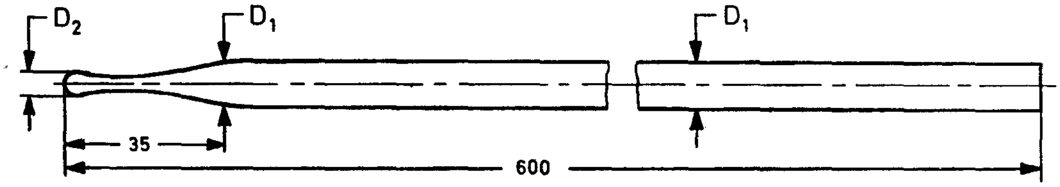
(Reaffirmed 2001)

SPECIFICATION FOR BOUGIE, OESOPHAGEAL

Surgical Instruments Sectional Committee, CPDC 11; Paediatric Surgery Instruments Subcommittee, CPDC 11 : 7 [Ref : Doc : CPDC 11 (1111)]

1. Scope — Dimensional and other requirements for Oesophageal bougie with olivery end used in general and paediatric surgery.

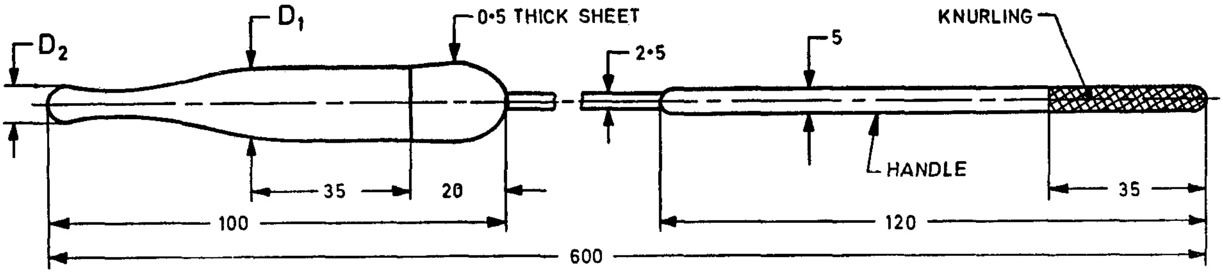
2. Shape and Dimensions — Typical shapes and dimensions shall be as shown in Fig. 1 and 2.



Dia D_1 = 3 to 10 in steps of 1
Dia D_2 = 1·5 to 5 in steps of 0·5

All dimensions in millimetres.

FIG. 1 BOUGIE, OESOPHAGEAL



Dia D_1 = 3 to 16 in steps of 1
Dia D_2 = 1·5 to 8 in steps of 0·5

All dimensions in millimetres.

FIG. 2 BOUGIE OESOPHAGEAL, WITH METALLIC HANDLE

2.1 *Tip* — The tip of the bougie shall be tapered and rounded off as shown in Fig. 1 and 2 to facilitate entry.

2.2 *Size Designation* — The size of the bougie shall be designated by its overall diameter expressed in millimetres and by the overall length expressed in centimetres. The size shall be expressed on the basis of the following example:

1·5 mm × 60 cm

3. Materials

3.1 The bougie shall be made from suitable rubber or plastics material and shall be sufficiently flexible to permit manipulation without fracture and at the same time maintain resistance to kinking and applied pressures.

3.2 The material shall be non-toxic and compatible with human tissues and shall not be detrimentally affected, physically or chemically, by body fluids and tissues with which they may come into contact.

3.3 The bougie shall be reasonably resistant to deterioration by methods of cleaning, disinfection and sterilization as recommended by the manufacturer or the supplier. They shall also be reasonably resistant to anaesthetic vapours and gases.

Adopted 29 September 1977	© January 1978, ISI	[redacted] Gr 1

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NEW DELHI 110002

3.4 For bougie with metallic handle, the metal portion shall be made from stainless steel conforming to designation 04Cr18Ni11 or 07Cr18Ni9 of IS : 1570 (Part V)-1972 'Schedules for wrought steels for general engineering purposes: Part V Stainless and heat-resisting steels (*first revision*)'.

4. Workmanship and Finish

4.1 The bougie shall be free from flash, surface irregularities, moulding, extrusion or other defects liable to adversely affect the function.

4.2 When examined under 2½ × magnification using adequate illumination, the bougie shall show complete freedom from chips of manufacturing materials.

4.3 The bougie shall be smooth at the junction between the metallic and non-metallic portions.

4.4 The bougie shall be clean and free from extraneous matter.

4.5 The soldering and welding, whenever provided, shall be neat and sound.

4.6 The stainless steel portion shall be polished bright and passivated.

5. Tests

5.1 *Pull Test* — It shall be applicable to the bougie with metallic handle. The handle portion and the tip shall be fixed in the jaws of a suitable tensile testing machine. A pull of 50 N shall be applied at the jaws for one minute. There shall be no damage at the joints to the bougie after the test.

5.2 *Corrosion Resistance* (*Copper Sulphate*) *Test* — Scrub the sample with soap and warm water, rinse in hot water and then dip in 90 percent ethyl alcohol. Dry the sample. Immerse in copper sulphate solution at room temperature for 6 minutes and wash off with fresh water or wet cotton wool.

5.2.1 The copper sulphate solution shall be prepared as follows:

Copper sulphate ($CuSO_4.5H_2O$)	4·0 g
Sulphuric acid (H_2SO_4) (sp gr 1·84)	10·0 g
Distilled water [*see* IS : 1070-1977 Specification for water for general laboratory use (*second revision*)]	90·0 ml

5.2.2 No red stains or spots on the sample shall be allowed but dulling of the polished surface may be permitted.

6. Marking — Each bougie shall be marked with the manufacturer's name, initials or recognized trade-mark.

6.1 *ISI Certification Marking* — Details available with the Indian Standards Institution.

7. Packing — Each bougie shall be wrapped in moisture-proof paper and put in a cardboard cartons or polyethylene bags. They may also be packed as agreed to between the purchaser and the supplier.

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